



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,131	09/20/2005	Karen McLachlan	2159.0640004/EKS/PAC/DLL	6721
53644 7590 03/05/2008 STERNE, KESSLER, GOLDSTEIN & FOX, P.L.L.C. 1100 NEW YORK AVE., N.W. WASHINGTON, DC 20005				
EXAMINER HARRIS, ALANA M				
ART UNIT		PAPER NUMBER		
1643				
MAIL DATE		DELIVERY MODE		
03/05/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/509,131

Applicant(s)

MCLACHLAN ET AL.

Examiner

Alana M. Harris, Ph.D.

Art Unit

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-42 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/86)
Paper No(s)/Mail Date ____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 2, 17 and one of claims 36-42, drawn to an isolated nucleic acid sequence expressed by human colon cancer cells. *Election of this Group requires the further election of single SEQ ID NO: for reasons described below.*

Group II, claim(s) 3 and 18, drawn to a primer mixture. *Election of this Group requires the further election of single SEQ ID NO: for reasons described below.*

Group III, claim(s) 4-6, drawn to a method of detecting colon cancer comprising detecting nucleic acid. Claim 4 will be examined with this Group to the extent the detection method implements a nucleic acid assay. *Election of this Group requires the further election of single SEQ ID NO: for reasons described below.*

Group IV, claim(s) 4 and 7-9, drawn to a method of detecting colon cancer comprising detecting an antigen. Claim 4 will be examined with this Group to the extent the detection method implements a protein assay. *Election of this Group requires the further election of single SEQ ID NO: for reasons described below.*

Group V, claim(s) 10, 11, 13, 14 and 16, drawn to an antigen expressed by human colon cancer cells. *Election of this Group requires the further election of single SEQ ID NO: for reasons described below.*

Group VI, claim(s) 12, 15, 19 and 20, drawn to a monoclonal antibody or antigen-binding fragment, thereof. *Election of this Group requires the further election of single SEQ ID NO: for reasons described below.*

Group VII, claim(s) 21, drawn to a method for treating colon cancer with comprises administering a ribozyme. Claim 21 will be examined with this Group to the extent a ribozyme is administered. *Election of this Group requires the further election of single SEQ ID NO: for reasons described below.*

Art Unit: 1643

Group VIII, claim(s) 21, drawn to a method for treating colon cancer with comprises administering an antisense oligonucleotide. Claim 21 will be examined with this Group to the extent an antisense oligonucleotide is administered. *Election of this Group requires the further election of single SEQ ID NO: for reasons described below.*

Group IX, claim(s) 22-24, drawn to a method for treating colon cancer with comprises administering a ligand that binds a nucleic acid molecule. Claim 21 will be examined with this Group to the extent a ligand is administered. *Election of this Group requires the further election of single SEQ ID NO: for reasons described below.*

Group X, claim(s) 25 and 26, drawn to a method for treating colon cancer comprising administering an antigen. *Election of this Group requires the further election of single SEQ ID NO: for reasons described below.*

Group XI, claim(s) 27-33, drawn to a method for treating colon cancer comprising administering a ligand that binds a protein. Claims 27-32 will be examined with the instant Group to the extent the ligand is a monoclonal antibody. *Election of this Group requires the further election of single SEQ ID NO: for reasons described below.*

Group XII, claim(s) 27-32 and 34, drawn to a method for treating colon cancer comprising administering a ligand that binds a protein. Claims 27-32 will be examined with the instant Group to the extent the ligand is a small molecule (other than a peptide). *Election of this Group requires the further election of single SEQ ID NO: for reasons described below.*

Group XIII, claim(s) 27-32 and 35, drawn to a method for treating colon cancer comprising administering a ligand that binds a protein. Claims 27-32 will be examined with the instant Group to the extent the ligand is a peptide. *Election of this Group requires the further election of single SEQ ID NO: for reasons described below.*

2. The inventions listed as Groups I-XIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Accession number AA922292 (May 19, 1998) and Hillier et al. (Genome Research 6(9): 807-828, 1996) comprising Accession number T54535 teach a fragment of SEQ ID NO: 2 having a size of at least 20 nucleotides in length, see alignments below. Moreover, each nucleic acid

Art Unit: 1643

sequence comprises different and distinct nucleotide residues, which encode different and distinct polypeptides. ***This is not a species election.***

Hence, with the election of one of Groups I-XIII Applicants are required to *further elect one nucleic acid, protein, primer or antibody bound by protein and its corresponding SEQ ID number.* The selected molecule or method group implementing the selected molecule is considered reading on one Group or Invention. Applicants are put on notice *this is not a species election.*

```

RST RESULT 1
AA922292/c
LOCUS      AA922292                413 bp    mRNA    linear    EST 19-MAY-1998
DEFINITION oh90a02.s1 NCI_CGAP_Co8 Homo sapiens cDNA clone IMAGE:1474250 3',
            mRNA sequence.
ACCESSION  AA922292
VERSION    AA922292.1   GI:3069601
KEYWORDS   EST.
FEATURES             Location/Qualifiers
     source           1. .413
                     /organism="Homo sapiens"
                     /mol_type="mRNA"
                     /db_xref="taxon:9606"
                     /clone="IMAGE:1474250"
                     /tissue_type="adenocarcinoma"
                     /lab_host="DH10B"
                     /clone_lib="NCI_CGAP_Co8"
                     /note="Organ: Colon; Vector: pT7T3D-PacI; 1st strand cDNA
                     was prepared from colon adenocarcinoma, and was then
                     primed with a Not I - oligo(dT) primer. Double-stranded
                     cDNA was ligated to Eco RI adaptors (Pharmacia), digested
                     with Not I and cloned into the Not I and Eco RI sites of
                     the modified pT7T3 vector. Library is normalized. Library
                     was constructed by Bento Soares and M. Fatima Bonaldo. "
ORIGIN

Query Match      58.0%; Score 394; DB 1; Length 413;
Best Local Similarity 99.8%; Pred. No. 7.4e-94;
Matches 405; Conservative 0; Mismatches 0; Indels 1; Gaps 1;

Qy      274  AGTGGAAATGAGATCCAGGAGAGGAAGGAGTTTCAGAAAGGCAGGAGCTGGTCCCTCTATGTC 333
          |||
Db      413  AGTGGAAATGAGATCCAGGAGAGGAAGGAGTTTCAGAAAGGCAGGAGCTGGTCCCTCTATGTC 354

Qy      334  ATGAAATGTAGAGGGTGTAGGCCAAGGAGGACCTGAGAGAGGTAATPAGATTGGTGTTT 393
          |||
Db      353  ATGAAATGTAGAGGGTGTAGGCCAAGGAGGACCTGAGAGAGGTAATPAGATTGGTGTTT 294

Qy      394  ACAGSCTGGTCCCTGTGGCCAGCCACCCGACCCACTTTAAAATATTCTCTACAAATGT 453
          |||
Db      293  ACAGSCTGGTCCCTGTGGCCAGCCACCCGACCCACTTTAAAATATTCTCTACAAATGT 235

Qy      454  TAATGTGTGAAGAGTTGCATGCCAGAAATATTTATGGCATCACTGTTGGTGGATACAGAAC 513

```

Art Unit: 1643

```

Db      234  ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||| 175
          TAAATGTTGTGAAGAGTTGTCATGCCAGAAATATTTATGGCATCAGTTGGTGGATACAGAAAC
Qy      514  ATTGGGAAACACCCCATTAATAGCAGAAATGCTAAATCTGGCCAGTGAATAGTATAGCTTT 573
          |||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      174  ATTGGGAAACACCCCATTAATAGCAGAAATGCTAAATCTGGCCAGTGAATAGTATAGCTTT 115
          |||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Qy      574  TTAAGAGGAGGCTGATGCTGCAATTCACTTTCAAGTTGTCACAAATGTAATTGCTAAAAAT 633
          |||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      114  TTAAGAGGAGGCTGATGCTGCAATTCACTTTCAAGTTGTCACAAATGTAATTGCTAAAAAT 55
          |||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Qy      634  ACAAAAAATGTTGCAGAAACCATATGATGAGAGAAACCCCTTTTCT 679
          |||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      54  ACAAAAAATGTTGCAGAAACCATATGATGAGAGAAACCCCTTTTCT 9
          |||||||||||||||||||||||||||||||||||||||||||||||||||||||||||

```

RST RESULT 2

```

T54535/c
LOCUS      T54535              422 bp      mRNA      linear      EST 06-FEB-1995
DEFINITION yb40f11.s1 Stratagene fetal spleen (#937205) Homo sapiens cDNA
            clone IMAGE:73677 3', mRNA sequence.
ACCESSION  T54535
VERSION    T54535.1 GI:656396
KEYWORDS   EST.
SOURCE     Homo sapiens (human)
            ORGANISM
              Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi;
              Mammalia; Eutheria; Euarchontoglires; Primates; Haplorrhini;
              Catarrhini; Hominidae; Homo.
REFERENCE  1 (bases 1 to 422)
            AUTHORS   Hillier, L., et al.
            TITLE      Generation and analysis of 280,000 human expressed sequence tags
            JOURNAL    Genome Res. 6 (9), 807-828 (1996)
            PUBMED     8889549
FEATURES   Location/Qualifiers
            source
              1..422
              /organism="Homo sapiens"
              /mol_type="mRNA"
              /db_xref="GDB:495342"
              /db_xref="taxon:9606"
              /clone="IMAGE:73677"
              /tissue_type="fetal spleen"
              /dev_stage="fetal"
              /lab_host="SOLR cells (kanamycin resistant)"
              /clone_lib="Stratagene fetal spleen (#937205)"
              /note="Organ: spleen; Vector: pBluescript SK-; Site_1:
              EcoRI; Site_2: XhoI; Cloned unidirectionally. Primer:
              Oligo dT. Pooled spleens. Average insert size: 1.0 kb;
              Uni-ZAP XR Vector; ~5' adaptor sequence: 5' GAATTCGGCAGCAG
              3' ~3' adaptor sequence: 5' CTCGAGTGTGTTTTTTTTTTTTTTT 3'"

```

ORIGIN

```

Query Match      46.0%; Score 312.4; DB 11; Length 422;
Best Local Similarity 92.3%; Pred. No. 4.6e-72;
Matches 370; Conservative 0; Mismatches 23; Indels 8; Gaps 4;

Qy      287  CCAGGAGAGGAAGGAGTTTC---AGAAAGCAGGAGCTGGTCC--TCTATGTCATGAAATG 341
          ||| ||||| ||||| ||||| ||||| ||||| ||||| ||||| ||||| |||||
Db      406  CCGGAGAGGGAAGNAGTTTCCAGAAAGGCAGGGAGCTGGNCCCTCCTATGTCATGAAATG 347
          ||||| ||||| ||||| ||||| ||||| ||||| ||||| ||||| |||||
Qy      342  TAGAGGGTGAGGCCC---AAGGAGGACCTGAGAGAGGTAATTAGATTGGTGTGTTA-CAGG 398
          ||||| ||||| ||||| ||||| ||||| ||||| ||||| ||||| |||||
Db      346  TAGAGGGTGAGGCCCCAAGGAGGNCCTTGAGAGAGGTAATTAGATTGGTGTGTTAAGCAGG 287
          ||||| ||||| ||||| ||||| ||||| ||||| ||||| ||||| |||||
Qy      399  CTGGTCCCTGTGGGCCAGGCCACCCACCCCACTTTAAATATTTACTCTACAAATGTTAATG 458
          ||||| ||||| ||||| ||||| ||||| ||||| ||||| ||||| |||||

```

Art Unit: 1643

```

Db      286 CTGGTCCCTGGGCCAGCCACCCACCCACTTTAAAAATATTACTCTACAAATGTTAATG 227
Qy      459 TGTGAAGAGTTGCATGCCAGAAATATTTATGGCATCAGTGTGGTGATACAGAACATTGG 518
      |||
Db      226 TGTGAAGAGTTGCATGCCAGAAATATTTATGGCATCAGTGTGGTGATACAGAACATTGG 167
Qy      519 GAAACAACCCATTAAATAGCAGAATGGTAAATCTGGCCAGTGAATAGTATAGCTTTTAAAA 578
      |||
Db      166 GAAACAACCCATTAAATAGCANCNGTAAATCTGGCCAGTGAATAGTATAGCTTTTAAAA 107
Qy      579 AGGAGGCTGATGCTCGAATTCACTTTCAAAGTTGTTCACAATGTATTGCTAAAAACAAA 638
      |||
Db      106 AGGAGGCTGATGCTCGAATTCACTTTCAAAGTTGTTCACAATGTATTGCTAAAAACAAA 47
Qy      639 AATGTTGCAGAACCATATGTATGAGAGAAACCCCTTTTTCT 679
      |
Db      46  ANTGTTGCAGAACCATATGTATGAGAGAAACCCCTTTTTNT 6

```

3. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The Examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are

subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

5. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is

(571)272-0831. The Examiner works a flexible schedule, however she can be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alana M. Harris, Ph.D.
22 February 2008
/Alana M. Harris, Ph.D./
Primary Examiner, Art Unit 1643